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Howmedica
OSTEONICS

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June 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 00N-0018
Orthopedic Devices; Reclassification of the Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis and the Knee Joint Femorotibial (Uni-compartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis

Dear Sir/Madam:

Howmedica Osteonics supports the Food and Drug Administration's efforts to reclassify the above-referenced product types from Class III to Class II with special controls. We believe that the 510(k) process, with the special controls cited in the reclassification order, are adequate to control the risks to health described in the literature for the knee joint patellofemorotibial metal/polymer porous coated uncemented prosthesis, and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis.

Howmedica Osteonics would like the FDA to consider the following comments in regard to the reclassification order:

1. The device descriptions for both knee products describe the porous coating as follows: *The porous coating has a volume porosity between 30 to 70 percent, and average pore size between 100 to 1,000 microns, interconnecting porosity, and a porous coating thickness of 600 to 1,500 microns."* Howmedica Osteonics believes that the porous coating thickness range should be changed to 500 to 1,600 microns. The lower limit of 500 microns is the initial value for the range cited in §888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. The increase on the upper end of the limit would increase the potential for bone ingrowth.

   Howmedica Osteonics also suggests that the volume porosity percentage be changed to 30 to 80 percent. This suggestion is based upon a recent scientific exhibit that investigated coatings with higher volume porosity.

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In an animal model, coatings with higher volume porosity showed more bone formation at the bone-implant interface than with porous materials with a lower volume porosity[1]. This slight modification in the volume porosity would potentially allow coatings with a greater likelihood for bone ingrowth to be introduced to the market.

2. The device descriptions listed in the current reclassification order are based on currently available porous coatings. Howmedica Osteonics believes that FDA should modify the order to indicate that future coatings which meet the parameters outlined in this reclassification order (i.e., volume porosity, average pore size, interconnecting porosity, and thickness) that can be demonstrated by mechanical testing, and/or animal testing, to be substantially equivalent to those currently available may be brought to market through the 510(k) process with the same special controls that are outlined in the current order. This would allow changes to be made in porous coating technology, but would require that newer coatings meet the current standards before human use. Human clinical trials should be required only for those coatings, which cannot demonstrate substantial equivalence to those coatings listed in the current order.

Thank you very much for your consideration of these comments. If you have any questions please contact Margaret F. Crowe, Regulatory Affairs Consultant, at (201) 507-6922.

Sincerely yours,
Howmedica Osteonics Corp.

Elizabeth Staub
Vice President
Quality Assurance, Regulatory Affairs, and
Clinical Research

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1. Bobyn, JD, Hacking, SA, Chan SP, Toh, K-K, Krygier, JJ, Tanzer, M. "Characterization of a New Porous Tantalum Biomaterial for Reconstructive Orthopaedics", Scientific Exhibit at the 1999 Annual Meeting of the American Academy of Orthopaedic Surgeons

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